Midazolam

in 0.8% Sodium Chloride Injection

B BRAUN
SHARING EXPERTISE

WARNING: PERSONNEL AND EQUIPMENT FOR MONITORING AND RESUSCITATION, AND RISKS FROM CONCOMITANT USE WITH OPIOID ANALGESICS AND OTHER SEDATIVE-HYPNOTICS

See full prescribing information for complete boxed warning.

- **Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure should administer Midazolam in Sodium Chloride Injection.**
- **Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation.**
- **Resuscitative drugs, and age- and size-appropriate equipment for bag/valve/mask assisted ventilation must be immediately available during administration of Midazolam in Sodium Chloride Injection.**
- **Continuously monitor vital signs during sedation and through the recovery period.**
- **Concomitant use of benzodiazepines with opioid analgesics may result in profound sedation, respiratory depression, coma, and death. Continuously monitor patients for respiratory depression and depth of sedation.**

36-month shelf life.

Preservative-free solution.

No reconstitution required.

Enhanced barcode for product scanning.

NOT MADE WITH DEHP OR PVC

Not made with DEHP, PVC or natural rubber latex.

Product Code	NDC Number	Product	Volume	McKesson Drug OE	Cardinal Drug OE	Cencora OE	Morris and Dickson OE
DM8005	0264-8005-31	Midazolam in 0.8% Sodium Chloride Injection, 50 mg/50 mL	50 mL	Coming Soon	6079404	10304310	490367
DM8002	0264-8002-32	Midazolam in 0.8% Sodium Chloride Injection, 100 mg/100 mL	100 mL	Coming Soon	6079412	10304286	490326

Important Safety Information
(for full Prescribing Information refer to Package Insert)

Midazolam in 0.8% Sodium Chloride Injection

WARNING: PERSONNEL AND EQUIPMENT FOR MONITORING AND RESUSCITATION, AND RISKS FROM CONCOMITANT USE WITH OPIOID ANALGESICS AND OTHER SEDATIVE-HYPNOTICS

See full prescribing information for complete boxed warning.

- **Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure should administer Midazolam in Sodium Chloride Injection.**
- **Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation.**
- **Resuscitative drugs, and age- and size-appropriate equipment for bag/valve/mask assisted ventilation must be immediately available during administration of Midazolam in Sodium Chloride Injection.**
- **Continuously monitor vital signs during sedation and through the recovery period.**
- **Concomitant use of benzodiazepines with opioid analgesics may result in profound sedation, respiratory depression, coma, and death. Continuously monitor patients for respiratory depression and depth of sedation.**

INDICATIONS AND USAGE

Midazolam in Sodium Chloride Injection is a benzodiazepine indicated for:

- Continuous intravenous infusion for sedation of intubated and mechanically ventilated adult, pediatric, and neonatal patients as a component of anesthesia or during treatment in a critical care setting.

CONTRAINDICATIONS

Midazolam in Sodium Chloride Injection is contraindicated in patients with:

- Known hypersensitivity to midazolam.
- Acute narrow-angle glaucoma.

WARNINGS AND PRECAUTIONS

Risk of Cardiorespiratory Adverse Reactions
Serious cardiorespiratory adverse reactions have occurred, sometimes resulting in death or permanent neurologic injury.

Risk of Paradoxical Behavior
Agitation, involuntary movements (including tonic/clonic movements and muscle tremor), hyperactivity and combativeness have been reported in both adult and pediatric patients.

Risk of Dependence and Withdrawal with Long-Term Use of Midazolam in Sodium Chloride Injection
Use for several days to weeks may lead to physical dependence to midazolam. Do not abruptly discontinue midazolam. Gradually taper the dosage using a tapering schedule that is individualized to the patient.

Debilitation and Comorbid Considerations
Higher risk adult and pediatric surgical patients, elderly patients and debilitated adult and pediatric patients require lower dosages, whether or not concomitant sedating medications have been administered.

Risk of Intra-Arterial Injection
There have been limited reports of intra-arterial injection of midazolam. Adverse events have included local reactions, as well as isolated reports of seizure activity in which no clear causal relationship was established.

Impaired Cognitive Function
Because of partial or complete impairment of recall, patients should not operate hazardous machinery or a motor vehicle until drug effects have subsided.

Risk of Hypotension and Seizure in Preterm Infants and Neonates
Avoid rapid injection in the neonatal population.

Neonatal Sedation and Withdrawal Syndrome
Receiving Midazolam in Sodium Chloride Injection during pregnancy can result in neonatal sedation and/or neonatal withdrawal.

Pediatric Neurotoxicity
In developing animals, exposures greater than 3 hours cause neurotoxicity. Weigh benefits against potential risks when considering elective procedures in children under 3 years old.

ADVERSE REACTIONS

The most common adverse reactions (≥15%) were decreased tidal volume, decreased respiratory rate, and apnea.

To report SUSPECTED ADVERSE REACTIONS, contact B. Braun Medical Inc. at 1-833-425-1464 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

DRUG INTERACTIONS

Opioid Analgesics and Other Sedative Hypnotics: Risk of respiratory depression is increased.

Cytochrome P450-3A4 Inhibitors: May result in prolonged sedation due to decreased plasma clearance of midazolam.

USE IN SPECIFIC POPULATIONS

Lactation: A lactating woman may pump and discard breast milk for 4 to 8 hours after treatment with midazolam

This Important Safety Information does not include all the information needed to use Midazolam in Sodium Chloride Injection safely and effectively. Please see package insert for full prescribing information, including BOXED WARNING, for Midazolam in Sodium Chloride Injection.

Distributed by:
B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862
Prepared in Canada. API from Israel.

Rx only LD-870-2 09/2025